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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,651	04/15/2005	Ho-Jin Kang	B10A5100.4	1542

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EXAMINER	
WARE, DEBORAH K	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,651	KANG ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-7 and 9-10 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2008, has been entered.

Response to Amendment

The amendment filed December 4, 2008, has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 (8 now canceled in amendment of April 7, 2008), in the reply filed on July 3, 2007, is acknowledged.

Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 3, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-7 and 10 are rendered vague and indefinite for the recitation of “with at least the characteristics according to claim 10b and 10d" because not only is claim 10 indefinite for the recitation of "selecting and culturing a strain" step, "a substance" defined as having cytotoxic activity but no description as to what the substance is per se, confusing and inconsistent procedures for step b. for evaluating the substance, and the evaluating step d., etc. and overall lack of clear and distinct recitation of process steps for claim 10; the claim 2 is unclear because recitation of "10b and 10d" is unclear as to what the characteristics are to be in claim 2 from which claims 3-7 depend. Also "strain capability" lacks antecedent basis in claim 10. Further, "samples from the test mammal" renders claim 10 indefinite because it is unclear what samples are tested, per se. The overall metes and bounds of the claims are unclear.

Response to Arguments

The arguments and amendments are not deemed sufficient to overcome the rejection because new issues have been raised regarding the newly presented amended claims in the RCE.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **newly cited** Cavadini et al (5968569).

Claims drawn to products for improving immune function in mammals, comprising selecting a strain of Lactobacillus reuteri which has these characteristics. The product comprises a strain with these characteristics and is in the form of a food, tablet, dietary supplement, confectionery, or an oral drug, etc.

Cavadini et al teach a method of producing a product for improving immun-function in mammals comprising a probiotic wherein the probiotic can be Lactobacillus reuteri, see column 1, lines 25-30 and column 3, lines 1 and 22. The probiotic can be encapsulated, column 3, line 30. The probiotic microorganism strain cells are contained in food, column 6, lines 17-19 and column 6, line 37.

Also a nutritional or dietary supplement is disclosed, note column 6, line 51. Coatings for the product are disclosed at column 8, line 28, of which pellets (i.e. tablets) are disclosed, see line 45. The probiotic microorgansims can also be in a sugar carrier (i.e. confectionery), note column 2, lines 19 and 24; and also column 5, lines 25-28. Since the disclosed product has the effect of the probiotic microorganism it can contain, such as probiotic bacteria for which can activate the immune functions of a mammal; and it can also be in the form of an oral drug, column 1, lines 25-30.

The cited disclosure clearly teaches that a probiotic can be selected from a Lactobacillus reuteri microorganism which can be any strain thereof. Also the probiotic microorganism clearly possess immune-improving function and exhibit good neutralizing effects of toxic amine compounds which means that they have an inhibitory effect on toxin binding in the mammals. No disclosure is discussed in terms of the probiotics' effect on CD4+ cell recruitment, however, it is believed by the Examiner to be an inherent feature of the selected probiotic strain because it is disclosed to have the ability to activate the immune functions of a mammal and also to inhibit production of toxic amine compounds in the mammal.

The claims are considered to be identical to the teachings of Cavadini et al and are, therefore, anticipated by the teachings of the reference. The selected strain of Lactobacillus reuteri disclosed by Cavadini et al will inherently possess at least the characteristics of exhibiting good toxin binding and neutralizing effect; and exhibit good CD4+ recruitment because the probiotic microorganism strains are disclosed to inhibit the growth and activity of putrefying bacteria and hence the production of toxic amine compounds and to activate immune function in a mammal. Lactobacillus reuteri is further disclosed to be a suitable probiotic microorgansim to be contained by the disclosed products which include food, capsules and pellets which are functionally similar to tablets,, dietary supplement, confectionery forms of the product, and an oral drug.

However, in the alternative that there is some difference between the claims and the cited Cavadini et al reference, then such difference is considered to be so slight as to render the claims prima facie obvious over Cavadini et al. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a product for improving immune-function in mammals comprising selecting a strain of Lactobacillus reuteri and formulating the product to contain cells of the strain because the reference clearly teaches that these strains are good probiotics capable of improving immune-function in mammals.

The strains will have to exhibit good toxin binding the neutalizing effect as well as good CD4+ cell recruitment in order to be effective for improvement of immune-function. Also it is disclosed that the inhibitory effect of putrefying bacteria in the mammal also is

indicative of inhibiting toxic amine compounds. Therefore, good toxin binding and neutralizing effect are intrinsic to the teachings of the reference and further CD4+ cell recruitment will also be an intrinsic effect of the selected probiotic.

Furthermore, to formulate the probiotic in the form of a food, confectionery, tablet, dietary supplement, oral drug, etc. is an obvious modification at the very least even if these claimed features are not considered to be disclosed. However, in reference to the latter it is believed by the Examiner that these formulations are clearly disclosed, or are at least suggested, by the teachings of the reference.

Response to Arguments

Applicant's arguments filed December 4, 2008, have been fully considered but they are not persuasive. The argument that the probiotics of the cited disclosure do not teach specific characteristics of the claim is noted, however, these characteristics are believed by the Examine to be an inherent feature of the disclosed probiotic Lactobacillus reuteri because probiotic are well known in the art to promote a healthy immune system. The reference clearly teaches that these probiotics are formulated into products. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Thus, the rejection is sustained over these products.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 4, 5 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5 and 6 of copending Application No. 11/123,330. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are both drawn to products having improved immune function in mammals and the products contain the same lactic acid bacteria, Lactobacillus reuteri.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims are discussed above.

Copending claims are drawn to products for oral administration and nutritional products and can be Lactobacillus reuteri.

The claims of the instant case only differ from copending claims in the scope of the claimed subject matter because they both require products containing the same bacteria.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the pending claim products based upon a reading of the copending claims which teach similar products capable of improved immune function in mammals containing the same Lactobacillus reuteri.

Clearly one of skill would have been motivated by the copending claims to provide for the claimed products of the instant case. Thus, the claims are rendered prima facie obvious over the copending claims.

All art-rejected claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed, however, claim 10 is rendered free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/
Deborah K. Ware
Examiner
Art Unit 1651